

REMARKS

Entry of the foregoing amendments is respectfully requested.

Summary of Amendments

Upon entry of the foregoing amendments, claims 105, 141, 161-163, 180 and 199 are amended, whereby claims 105-208 continue to be pending. Claims 105, 163, 180, 207 and 208 are independent claims. Support for the amended claims can be found throughout the present specification and in particular, in paragraph [0068] on page 12 thereof.

Applicants emphasize that the amendments to claims 105, 141, 161-163, 180 and 199 are without prejudice or disclaimer, and Applicants expressly reserve the right to prosecute these claims in their unamended form in one or more continuation and/or divisional applications.

Summary of Office Action

As an initial matter, Applicants note with appreciation that a signed and initialed copy of the Form PTO-1449 submitted in the Third Supplemental Information Disclosure Statement filed October 31, 2005 has been returned together with the present Office Action.

Applicants also note with appreciation that all previously applied rejections have been withdrawn.

Claims 161 and 162 are objected to because of alleged informalities.

Claims 141 and 199 are rejected under 35 U.S.C. § 112, second paragraph, as

P24008.A10

being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 105-116, 119, 124, 125, 128-131, 133-136, 139-141, 147, 148, 163, 164, 174-178, 188-191, 193-195 and 197-199 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent Application Publication No. 2004/0241214 by Kirkwood et al. (hereafter "KIRKWOOD").

Claims 105-113, 119, 121, 122, 124, 125, 139-141, 143, 147, 148, 174, 176, 177, 179-186, 188-191 and 197-199 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Kania, WO 01/60599 A1 (hereafter "KANIA").

Claims 126, 127, 167, 192 and 206 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as allegedly being obvious over KIRKWOOD.

Claims 117, 118, 120-123, 132, 142-146, 152-162, 165, 168, 169, 171-173, 187 and 200-205 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over KIRKWOOD.

Claims 137, 138 and 196 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over KIRKWOOD and further in view of U.S. Patent No. 6,903,243 to Burton (hereafter "BURTON").

Claims 149-151, 170, 207 and 208 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over KIRKWOOD and further in view of U.S. Patent No. 6,333,093 to Burrell et al. (hereafter "BURRELL").

Claims 105-208 are provisionally rejected under the non-statutory doctrine of

P24008.A10

obviousness-type double patenting as allegedly being unpatentable over claims 1-20 and claims 1-34 of copending Application Nos. 11/255,956 and 11/255,957.

Response to Office Action

Withdrawal of the objections and rejections of record is respectfully requested, in view of the foregoing amendments and the following remarks.

Response to Objection to Claims

Claims 161 and 162 are objected to because of the term “size” recited therein. The Examiner requests that this term be replaced by the term “surface area”. Applicants, while disagreeing with the Examiner in this regard, have complied with this request by amending claims 161 and 162 correspondingly. Accordingly, this objection is moot.

Response to Rejection of Claims under 35 U.S.C. § 112, Second Paragraph

Claims 141 and 199 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The rejection alleges that it is unclear as to whether or not the term “sheet-like structure” recited in these claims includes sheets.

Although Applicants disagree with the Examiner in this regard, claims 141 and 199 submitted herewith are amended and recite “sheet” instead of “sheet-like”. Accordingly, this rejection is moot.

Response to Rejection of Claims under 35 U.S.C. § 102(e) over KIRKWOOD

Claims 105-116, 119, 124, 125, 128-131, 133-136, 139-141, 147, 148, 163, 164, 174-178, 188-191, 193-195 and 197-199 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by KIRKWOOD. The rejection essentially asserts that KIRKWOOD teaches a wound dressing comprising a liquid-permeable, apertured wound-facing surface with a plurality of particles comprising silver located behind the wound-facing surface. The examiner equates the applied apertured fabric to the mesh structure recited in the rejected claims. Furthermore, the rejection alleges that KIRKWOOD teaches that an absorbent may be located behind the layer of silver particles and that all of the additional elements recited in the rejected claims are disclosed in KIRKWOOD as well. The rejection further alleges that according to KIRKWOOD a layer of microspheres may be coated on the back of the apertured sheet. The Examiner equates this layer comprising silver microspheres to the instantly claimed "silver coating" as it allegedly is a coating layer comprising silver.

This rejection is respectfully traversed. Amended independent claims 105, 163 and 180 make it clear that the silver coating recited therein is a coating of elemental silver as such, i.e., without any other materials (see, e.g., paragraph [0068] of the present specification).

On the other hand, from paragraphs [0052] and [0053] of KIRKWOOD relied on in the present rejection it becomes clear that a coating of colloidal silver according to KIRKWOOD would not consist of colloidal silver as such, but would comprise microparticles or microspheres loaded with colloidal silver.

The microparticles/microspheres of KIRKWOOD that are loaded with therapeutic agents such as, *inter alia*, colloidal silver are discussed in detail in paragraphs [0046] to [0051] of KIRKWOOD. A specific example thereof is described in paragraph [0070] of KIRKWOOD, i.e., cross-linked gelatin microspheres having an effective minimum diameter of from about 0.4 mm to about 1 mm and containing 3% w/w of chlorhexidine antiseptic.

It is submitted that for at least all of the foregoing reasons, KIRKWOOD does not anticipate the subject matter of any of the claims submitted herewith, wherefore the claim rejection under 35 U.S.C. § 102(e) over KIRKWOOD should be withdrawn, which action is respectfully requested.

Response to Rejection of Claims under 35 U.S.C. § 102(e) over KANIA

Claims 105-113, 119, 121, 122, 124, 125, 139-141, 143, 147, 148, 174, 176, 177, 179-186, 188-191 and 197-199 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by KANIA. The rejection alleges, *inter alia*, that KANIA “teaches a multilayer antimicrobial article comprising a layer of polyethylene mesh **16** and a polymeric layer **12** with a layer of silver in between **14** (page 7, lines 4-20 and page 9, lines 11-24)”.

Applicants respectfully traverse this rejection as well. Neither page 7, lines 4-20 nor page 9, lines 11-24 of KANIA supports the allegation that this document teaches a multilayer antimicrobial article comprising a layer of silver **14** between a layer of polyethylene mesh **16** and a polymeric layer **12**. Specifically, these two passages of KANIA state, *inter alia*:

In a preferred embodiment, the present invention is a multilayer composition 10 in sheet form, including a layer 12 of polymer material and a silver-containing layer 14 (shown schematically in Fig.1A). Layer 12 may comprise a polymeric gel composition, for example, a block copolymer and, optionally, mineral oil as described below. ... The silver layer 14 may be added by coating the polymeric gel composition with silver or incorporating silver therein; alternatively, a silver-containing fabric 16 such as silver nylon material may be attached to the polymeric gel composition (Fig. 1B). While silver is preferred, other metals and compounds with useful antimicrobial properties may also be useful. ...

One or both sides of layer 12 are at least partially coated with silver by any convenient technique, including but not limited to vapor coating, aerosolized deposition, sputter coating, magnetron sputtering, vacuum evaporation, chemical deposition, plating, ion plating, or other techniques known in the art. Alternatively, the silver may be carried by a layer 16 that incorporates or is coated with useful amounts of silver. For example, layer 16 may comprise a woven, knitted, or nonwoven silver-plated fabric, or a fabric made up of a mat or mesh of fibers. Alternatively, the fabric may be made of a combination of silver-coated (or silver-impregnated) and plain fibers. Suitable materials for layer 16 include silver-impregnated warp knit nylon fabric, silver-impregnated nylon pile fabric, and other fabrics made by Omnishield, Inc., Swift, Inc., Sauquoit Industries, and other manufacturers. Other useful fabrics or textiles include those fabricated of natural fibers (cotton, silk, jute, linen, etc.), synthetic fibers (polyethylenes, rayons, acrylics, modacrylics, and others), and combinations thereof that contain useful amounts of silver.

Emphases added. Accordingly, what KANIA actually discloses is that layer 12 can be coated with elemental silver (i.e., a silver layer 14) or (alternatively) a silver-containing fabric 16 may be attached to layer 12. Corresponding embodiments are shown in Figures 1A and 1B of KANIA.

In view of the foregoing, KANIA does not anticipate any of the claims submitted herewith for at least two reasons: First, KANIA does not teach or suggest disposing a silver coating between the two layers 12 and 16. Second, the multilayer antimicrobial article of KANIA would appear to necessarily have antimicrobial metal (silver) on at least one

P24008.A10

exterior surface thereof. This is readily evident in the case of the embodiment of Fig. 1A of KANIA where a silver coating constitutes at least a part of one of the outer surfaces of the article. In the embodiment of, for example, Fig. 1B the materials for layer 16 are impregnated with silver or otherwise contain silver (see, e.g., the explanations on pages 9-11 of KANIA). Accordingly, it would appear that there is always some elemental silver exposed on the outer surface of layer 16 which constitutes an outer surface of the article.

Applicants submit that for at least all of the reasons set forth above, KANIA does not anticipate the subject matter of any of the claims submitted herewith, wherefore the claim rejection under 35 U.S.C. § 102(b) over KANIA is unwarranted and should be withdrawn.

Response to Rejection of Claims under 35 U.S.C. § 102(e)/103(a) over KIRKWOOD

Dependent claims 126, 127, 167, 192 and 206 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as allegedly being obvious over KIRKWOOD. The rejection concedes that the features recited in the rejected claims are not explicitly disclosed in KIRKWOOD, but essentially alleges that these features are either inherent in the disclosure of KIRKWOOD or rendered obvious thereby.

This rejection is respectfully traversed as well. As set forth in detail above with respect to the claim rejection under 35 U.S.C. § 102(e) over KIRKWOOD, this document fails to disclose at least one feature of independent claims 105, 163 and 180 submitted herewith, i.e., a coating of antimicrobial metal in elemental form as such.

P24008.A10

Neither does KIRKWOOD suggest that the microparticles/microspheres loaded with one or more therapeutic agents which are discussed in detail at page 4 of KIRKWOOD can be dispensed with, i.e., that the therapeutic agents can be used as such. On the contrary, these agent-loaded microparticles/microspheres are an integral and critical part of the invention of KIRKWOOD because they must be big enough to be held back by the wound contacting sheet in the dry state and must be small enough to pass through the opened or enlarged apertures of the wound contacting sheet in the presence of wound exudates.

At least for all of the foregoing reasons, the claim rejection under 35 U.S.C. § 102(e)/103(a) over KIRKWOOD is without merit, wherefore withdrawal thereof is respectfully requested.

Response to Rejection of Claims under 35 U.S.C. § 103(a) over KIRKWOOD in View of BURRELL

Claims 149-151, 170, 207 and 208 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over KIRKWOOD and further in view of BURRELL. The rejection concedes that KIRKWOOD is silent as to the anti-bacterial silver being provided as a sheet or film between the first and second layers and the incorporation of a layer of aluminum between the silver layer and the first layer. However, the rejection alleges that BURRELL teaches a multilayer anti-microbial material formed to produce an interference color, and thus an indicator of antimicrobial effect. According to the rejection, BURRELL provides a base layer of a partly reflective layer (e.g., aluminum) and a top layer containing

P24008.A10

at least one antimicrobial metal (preferably silver). The Examiner takes the position that it would have been obvious to one of ordinary skill in the art to modify the antimicrobial wound dressing of KIRKWOOD with the motivation of providing the wound dressing with a visible indicator of anti-microbial activity, so as to minimize the overapplication of antimicrobial agents and unnecessary wound dressing removal.

This rejection is respectfully traversed as well. In particular, the Office Action relies on col. 13, lines 51-57 and col. 12, lines 8-55 of BURRELL and essentially alleges that the antimicrobial material of BURRELL (top and bottom layers) may be arranged between the first wound-facing layer 12 and a second absorbent layer depicted in Fig. 2 of BURRELL. "This teaching provides for a layer of aluminum followed by a layer of silver between a perforated polyethylene film and an absorbent layer". Page 9, first paragraph of the present Office Action. Applicants respectfully disagree with the Examiner in this regard. The passage from col. 13, line 52 to col. 14, line 5 of BURRELL states:

The wound dressing of this invention preferably includes an anti-microbial coating formed from an anti-microbial metal. The coating is applied to one or more of the layers 12, 14, 16, but is most preferably applied at least to the first, wound facing layer 12 to provide a localized anti-microbial effect next to (sic) the wound. The coating may also be applied to the outer layer 16 for additional anti-microbial effect.

The coating is most preferably formed with atomic disorder in accordance with the procedures set out above and as described in U.S. Pat. No. 5,454,886. Most preferably, the coating is formed as a multiplayer (sic) anti-microbial coating, as set above, to produce an interference colour. In this way, the coating provides not only an anti-microbial effect to limit infection, but also acts as an indicator of activation of the dressing. As the top layer of the coating is activated by contacting an electrolyte such as wound exudate, blood or added water, even minor dissolution of the anti-microbial metal results in a detectable colour change, indicating that an anti-microbial effect is being provided. If there is no colour change, additional moisture might be provided to the coating by adding water, until a colour change is detected.

P24008.A10

Emphases added. Even if BURRELL were taken to suggest using the multilayer antimicrobial indicator as antimicrobial coating, one of ordinary skill in the art will readily understand that arranging the multilayer indicator between two layers does not serve any useful purpose because in this case there is no visible color change due to the indicator being hidden between two layers.

Accordingly, it is apparent that the only location of the indicator for the wound dressing depicted in Fig. 2 of BURRELL which would make it possible to detect a color change is the outer wound-facing surface of layer 12.

Further, nothing in BURRELL specifically teaches or suggests arranging the antimicrobial indicator thereof between two layers of an antimicrobial composite. For example, claim 18 recites a specific arrangement, i.e.,

The wound dressing of claim 17, wherein the multi[p]layer anti-microbial coating is provided on both the first and third layers, such that a colour change is delectable (sic) on either side of the wound dressing.

Emphasis added. Accordingly, claim 18 of BURRELL calls for an arrangement wherein the multilayer antimicrobial coating is provided on both outer surfaces (i.e., the first and third layers) of the multilayer wound dressing of claim 17. Claim 18 also indicates the reason why it is important to have the multilayer antimicrobial coating on the outside of the wound dressing, i.e., detectability.

In view of the foregoing, even a combination of the teachings of KIRKWOOD and BURRELL does not render obvious the subject matter of the rejected claims.

Additionally, Applicants point out that the indicator composite of BURRELL serves a dual function, i.e., it is the source of antimicrobial metal and at the same time indicates by

P24008.A10

a color change whether the antimicrobial metal (e.g. silver) has been released from the top layer of the indicator composite. See, e.g., the abstract of BURRELL. The composite of KIRKWOOD, on the other hand, already contains an antimicrobial substance (in the form of microparticles/microspheres which are loaded with antimicrobial substance), wherefore the inclusion of yet another source of antimicrobial substance (i.e., the antimicrobial indicator composite of BURRELL) would not appear to be of any advantage, but rather would unnecessarily complicate things.

In particular, two different sources of antimicrobial substances (the antimicrobial particles of KIRKWOOD and the antimicrobial indicator composite of BURRELL) which release the antimicrobial substance(s) according to different mechanisms and at different rates would require a careful matching (if possible at all) of the release profiles of the microparticles/microspheres and the indicator composite in order to ensure that the corresponding composite does not release too much and not too little of the antimicrobial substances per time unit. For this reason alone, there is no motivation, but rather a disincentive to include the antimicrobial indicator composite of BURRELL in the antimicrobial composite of KIRKWOOD.

For at least all of the foregoing reasons, the antimicrobial composite recited in any of the present claims is not rendered obvious by KIRKWOOD in view of BURRELL. Accordingly, it is respectfully requested that the Examiner withdraw the claim rejection under 35 U.S.C. § 103(a) over KIRKWOOD in view of BURRELL.

Response to Remaining Claim Rejections under 35 U.S.C. § 103(a)

The remaining claim rejections under 35 U.S.C. § 103(a) set forth in the present Office Action which are not already addressed above relate exclusively to dependent claims. As pointed out above, all of the independent claims submitted herewith are neither anticipated nor rendered obvious by any of the documents cited in the present Office Action. Accordingly, at least for the same reasons as set forth above with respect to the independent claims, the claims which depend from these independent claims are neither anticipated nor rendered obvious, either. Thus, there appears to be no need to discuss any further reasons why the rejected dependent claims are allowable. However, Applicants' silence in this respect must not be construed as admission that any of the arguments relating to the rejection of the dependent claims set forth in the present Office Action (and in general, any of the arguments and allegations not specifically addressed in this response) is meritorious. For example, many of the rejections of the dependent claims are based on presumptions of inherency. The Examiner has not supported any of the corresponding presumptions by documentary evidence, and for this reason alone, the corresponding rejections are without a sound basis.

Response to Provisional Claim Rejection under Doctrine of Obviousness-Type Double-Patenting

Claims 105-208 are provisionally rejected under the non-statutory doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-20 and claims 1-34 of copending Application Nos. 11/255,956 and 11/255,957.

P24008.A10


Applicants respectfully request that this rejection be held in abeyance until the Examiner has indicated allowable subject matter. Applicants will then decide whether it is necessary to file a Terminal Disclaimer in the present application.

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance, which action is respectfully requested. If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

April 20, 2006
GREENBLUM & BERNSTEIN, P.L.C.
1950 Roland Clarke Place
Reston, VA 20191
(703) 716-1191

Respectfully submitted,
Peter HILFENHAUS et al.



Neil F. Greenblum
Reg. No. 28,394

Heribert F. Muensterer
Reg. No. 50,417